

### **REMARKS**

Applicants thank the Examiner for considering the amendment to the claims and specification filed by the Applicants on February 5, 2007. Applicants also thank the Examiner for withdrawing the previous rejections and objections that are not restated in this Office Action, and for her helpful suggestions throughout the Office Action.

#### **The Claim Amendments**

Applicants have, following the Examiner's suggestion, amended claims 4, 7, 8, 9, 17, 22 and 60-65. The amendments are not new matter.

Applicants have amended claims 4, 7-9, 17, 22 and 60-65 to clarify that the polyarginine containing crystal of human growth hormone (hGH) is produced from the 1-191 native hGH or the 1-192 N-terminal methionine native hGH. This amendment does not encompass new matter. See, e.g., page 11, lines 23-26. All the other remaining claims depend, indirectly or directly, from claim 4 or recite the elements of claim 4.

Claims 4, 7-10, 17-22 and 60-65 are now pending.

#### **The Rejections**

##### ***1. §112, First Paragraph***

###### ***(i) Enablement***

The Examiner has maintained her rejection of claims 4, 7-10 and 17-22 under 35 U.S.C. §112, first paragraph, and included new claims 62-65 in the rejection, because the specification allegedly does not enable the skilled worker to make and use

the invention commensurate with the scope of the claims. Specifically, the Examiner asserts that the specification does not reasonably provide enablement for all polyarginine hGH crystals or crystal derivatives because the specification only sufficiently describes three polyarginine hGH crystals and only teaches how to make crystals from two recombinant sources.

Applicants disagree. However, solely to advance prosecution, applicants have amended the claims to recite two forms of hGH: 1-191 native hGH and 1-192 methionyl native hGH. As amended, the claims are enabled by the specification. The specification teaches how to make polyarginine containing crystals from the 191 and 192 forms of native hGH and sufficiently describes the crystallization parameters such that a skilled artisan would not have to perform undue experimentation. The specification provides a number of Examples that describe preparing polyarginine containing crystals of native hGH under diverse conditions and crystallization buffers. See Examples 19, 21 and 27. Example 19 mixes sodium rhGH crystals with polyarginine. Example 21 mixes calcium acetate-PEG-hGH crystals with polyarginine. Example 27 crystallizes hGH with sodium acetate and polyarginine. In each example, crystals were produced. Thus, the specification provides substantial and specific teachings that enable the production of polyarginine containing crystals from the recited hGHs.

In view of these amendments and arguments, applicants request that the Examiner reconsider and withdraw her enablement rejection.

**(ii) Written Description**

Claims 4, 7-10, 17-22 and new claims 62-65 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. Specifically, the

Examiner contends that the claimed genus of crystals is not sufficiently described.

Applicants disagree, but, solely to advance prosecution, applicants have amended the claims to overcome the rejection.

Applicants have amended the claims to direct them to polyarginine containing crystals of two hGHs: 1-191 native hGH and 1-192 methionyl native hGH. As amended, the specification describes the claimed hGH crystals. See Examples 19, 21 and 27.

In view of these amendments and arguments, applicants request that the Examiner reconsider and withdraw her written description rejection.

2. **Provisional Double Patenting**

Claim 4 stands rejected for provisional double patenting in view of claims 1, 2, 4, 7, 9 and 10 of the copending application 11/169,956. Because neither claim 4 of this application nor any of claims 1, 2, 4, 7, 9 and 10 of the copending application has issued, the filing of a Terminal Disclaimer is premature.

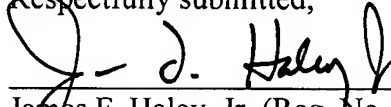
Applicants will file a Terminal Disclaimer, if appropriate and required, before grant of the claims in this application and in the co-pending application.

**CONCLUSION**

Applicants request consideration of the amended claims in view of the foregoing remarks and allowance of those claims.

Should the Examiner feel that a telephone conference with applicants' representative would assist the Examiner, she is invited to telephone the undersigned at any time.

Respectfully submitted,



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